## Food and Drug Administration, HHS

- (2) Indications for use. For the relief of chronic nonproductive cough associated with tracheo-bronchitis, tracheitis, tonsillitis, laryngitis, and pharyngitis associated with inflammatory conditions of the upper respiratory tract.
- (3) Limitations. For oral use in dogs only. Repeat at intervals of 6 to 12 hours as required. If necessary, increase dose to a maximum of 0.5 milligram per pound of body weight. Treatment should not normally be required for longer than 7 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

 $[47~\mathrm{FR}~14702,~\mathrm{Apr.}~6,~1982,~\mathrm{as}~\mathrm{amended}~\mathrm{at}~53~\mathrm{FR}~27851,~\mathrm{July}~25,~1988]$ 

### $\S 520.260$ *n*-Butyl chloride capsules.

- (a)(1) Specifications. n-Butyl chloride capsules, veterinary contain 272 milligrams or 816 milligrams of n-butyl chloride in each capsule.
- (2) *Sponsor*. See No. 021091 in §510.600(c) of this chapter.
- (3) Conditions of use. (i) It is used for the removal of ascarids (Toxocara canis and Toxascaris leonina) and hookworms (Ancylostoma caninum, Ancylostoma braziliense, and Uncinaria stenocephala) from dogs and of the ascarid (Toxocara cati) and hookworm (Ancylostoma tubaeforme) from cats.
- (ii)(a) Animals should not be fed for 18 to 24 hours before being given the drug. Puppies and kittens should be wormed at 6 weeks of age. However, if heavily infested, they may be wormed at 4 or 5 weeks of age. Administration of the drug should be followed in ½ to 1 hour with a teaspoonful to a tablespoonful of milk of magnesia or 1 or 2 milk of magnesia tablets. Normal rations may be resumed 4 to 8 hours after treatment. Puppies and kittens should be given a repeat treatment in a week or 10 days. After that they should be treated every 2 months (or as symptoms reappear) until a year old. When the puppy or kitten is a year old, one treatment every 3 to 6 months is suffi-
- (b) For dogs or cats that have been wormed regularly, treatment every 3 to 6 months will be sufficient. If a dog or cat has not been wormed previously and has the symptoms of large roundworms a dose should be given and

- repeated in 10 days. Removal of hookworms may require 3 or 4 doses at 10-day intervals.
- (c) Puppies, dogs, cats, or kittens weighing 1 to 3 pounds should be given 2 capsules per dose which contain 272 milligrams of *n*-butyl chloride each. Such animals weighing 4 to 5 pounds should be given 3 such capsules. Animals weighing 6 to 7 pounds should be given 4 such capsules and animals weighing 8 to 9 pounds should be given 5 such capsules. Animals weighing 10 to 20 pounds should be given 3 capsules which contain 816 milligrams of nbutyl chloride each, animals weighing 20 to 40 pounds should be given 4 such capsules and animals weighing over 40 pounds should be given 5 such capsules with the maximum dosage being 5 capsules, each of which contains 816 milligrams of n-butyl chloride.
- (iii) A veterinarian should be consulted before using in severely debilitated dogs or cats and also prior to repeated use in cases which present signs of persistent parasitism.
- (b)(1) Specifications. n-Butyl chloride capsules contain 221, 442, 884, or 1,768 milligrams or 4.42 grams of n-butyl chloride in each capsule.  $^1$
- (2) Sponsors. See No. 023851 in §510.600(c) of this chapter for 221, 442, 884, or 1,768 milligram or 4.42 gram capsules; No. 038782 for 884 or 1,768 milligram or 4.42 gram capsules; and No. 000069 for 221 milligram capsules.
- (3) Conditions of use. (i) It is used for the removal of ascarids (Toxocara canis and Toxascaris leonina) and hookworms (Ancylostoma caninum, Ancylostoma braziliense, and Uncinaria stenocephala) from dogs. <sup>1</sup>
- (ii)(a) Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal feeding may be resumed 4 to 8 hours after treatment. Animals subject to reinfection may be retreated in 2 weeks. 1

<sup>&</sup>lt;sup>1</sup>These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by \$514.111 of this chapter.

### § 520.300

- (b) The drug is administered orally to dogs. Capsules containing 221 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 11/4 pound of body weight. Capsules containing 442 milligrams of n-butyl chloride are administered to dogs weighing under 5 pounds at a dosage level of 1 capsule per 2½ pounds body weight. Capsules containing 884 milligrams of n-butyl chloride are administered to dogs as follows: Weighing under 5 pounds, 1 capsule; weighing 5 to 10 pounds, 2 capsules; weighing 10 to 20 pounds, 3 capsules; weighing 20 to 40 pounds, 4 capsules; over 40 pounds, 5 capsules. Capsules containing 1,768 milligrams of n-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 5 to 10 pounds. Capsules containing 4.42 grams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 40 pounds or over. 1
- (iii) A veterinarian should be consulted before using in severely debilitated dogs. <sup>1</sup>

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39858, Aug. 29, 1975; 44 FR 10059, Feb. 16, 1979; 54 FR 38515, Sept. 19, 1989; 55 FR 24556, June 18, 1990; 64 FR 15684, Apr. 1, 1999; 70 FR 50182, Aug. 26, 2005]

# § 520.300 Cambendazole oral dosage forms.

## §520.300a Cambendazole suspension.

- (a) Specifications. Each fluid ounce contains 0.9 gram of cambendazole.
- (b) *Sponsor*. No. 050604 in §510.600(c) of this chapter.
- (c) Conditions of use. (1) It is used in horses for the control of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); small strongyles (Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus); roundworms (Parascaris); pinworms. (Oxyuris); and threadworms (Strongyloides).
- (2) It is administered by stomach tube or as a drench at a dose of 0.9 gram of cambendazole per 100 pounds of body weight (20 milligrams per kilogram).
- (3) For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary.

For most effective results, re-treat in 6 to 8 weeks.

- (4) Not for use in horses intended for food.
- (5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.
- (6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975. Redesignated at 41 FR 1276, Jan. 7, 1976, and amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997]

#### §520.300b Cambendazole pellets.

- (a) Specifications. The drug is in feed pellets containing 5.3 percent cambendazole.
- (b) Sponsor. No. 050604 in  $\S510.600(c)$  of this chapter.
- (c) Conditions of use. (1) It is used in horses for the control of large strongyles (Strongylus vulgaris, S. edentatus, S. equinus); small strongyles (Trichonema, Poteriostomum, Cylicobrachytus, Craterostomum, Oesophagodontus); roundworms (Parascaris); pinworms (Oxyuris); and threadworms (Strongyloides).
- (2) Administer 20 milligrams cambendazole per kilogram body weight (6 ounces per 1,000 pounds) by mixing with normal grain ration given at one feeding. Doses for individual horses should be mixed and fed separately to assure that each horse will consume the correct amount.
- (3) For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.
- (4) Not for use in horses intended for food
- (5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.
- (6) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

 $[41~\mathrm{FR}~1276,\,\mathrm{Jan.}~7,\,1976,\,\mathrm{as}~\mathrm{amended}~\mathrm{at}~42~\mathrm{FR}~3838,\,\mathrm{Jan.}~21,\,1977;\,62~\mathrm{FR}~63270,\,\mathrm{Nov.}~28,\,1997]$ 

## §520.300c Cambendazole paste.

- (a) Specifications. The drug is a paste containing 45 percent cambendazole.
- (b) Sponsor. No. 050604 in §510.600(c) of this chapter.